

REMARKS

The Final Office Action dated July 27, 2004, has been received and reviewed.

Claims 1, 3-11, and 13-29 are currently pending and under consideration in the above-referenced application. Claims 30-44, 46, 48-64, 66-74, and 105-107 have been withdrawn from consideration and canceled without prejudice or disclaimer.

Reconsideration of the above-referenced application is respectfully requested.

Rejections Under 35 U.S.C. § 103(a)

Each of claims 1, 3-11, and 13-29 has been rejected under 35 U.S.C. § 103(a).

The standard for establishing and maintaining a rejection under 35 U.S.C. § 103(a) is set forth in M.P.E.P. § 706.02(j), which provides:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Isaka in View of Northrup

Claims 1, 3-5, 7, 9-11, 13, 16, 18-20, 22-25, and 29 stand rejected under 35 U.S.C. § 103(a) for being drawn to subject matter which is purportedly unpatentable over the subject matter taught in U.S. Patent 5,482,598 to Isaka et al. (hereinafter "Isaka"), in view of teachings from U.S. Patent 5,882,496 to Northrup et al. (hereinafter "Northrup").

Isaka teaches a chromatographic separation device that includes a silicon substrate and a single porous microchannel formed therein. *See, e.g.*, FIGs. 1-3. As the Office has noted, Isaka also suggests that "an IC for controlling conveyance or detection" may also be fabricated on the silicon substrate. Final Office Action, page 10, citing col. 2, lines 63-67. Isaka does not,

however, provide any specifics as to the types of ICs that would be fabricated to control conveyance (presumably of a sample) or detection.

Among other things, Northrup teaches an electrophoretic separation apparatus that includes porous columns formed internally within a silicon substrate. FIG. 8; col. 7, lines 40-43. Electrodes are positioned at opposite ends of the substrate so as to facilitate movement of the constituents of a sample along the lengths of the columns. Col. 7, lines 43-50.

Independent claim 1 is drawn to a sample separation apparatus that includes a substrate, matrices formed in the substrate, and at least one detector fabricated on the substrate and in communication with at least one of at least two porous regions. As proposed to be amended herein, independent claim 1 recites that the at least one detector comprises a thermal detector, a field effect transistor, or a voltage-application component and a current-detection component.

While Northrup does teach devices that may include thermopneumatic valves, which operate based on the temperature of a liquid to which the valves are exposed, Northrup does not teach or suggest that a detector comprising a temperature sensor may be fabricated on the substrate of the sample separation apparatus that are taught therein. Isaka also lacks any teaching or suggestion of a detector comprising a temperature sensor. Further, neither Isaka nor Northrup teaches or suggests that the apparatus disclosed therein may include a detector that comprises a field effect transistor or a voltage application component and current-detection component fabricated on the substrate thereof.

It is, therefore, respectfully submitted that the teachings of Isaka and Northrup do not support a *prima facie* case of obviousness against the subject matter to which amended independent claim 1 is drawn.

Claims 3-5, 7, 9-11, 13, 16, 18-20, 22-25, and 29 are each allowable, among other reasons, for depending either directly or indirectly from claim 1, which is allowable.

Claim 16 is additionally allowable because Isaka and Northrup both lack any teaching or suggestion that a processor may be fabricated on the substrates of the apparatus taught therein.

Claim 19 is further allowable because neither Isaka nor Northrup teaches or suggests a pump in communication with an end of a porous region of the apparatus taught therein.

Claim 20 depends from claim 19 and is also allowable since neither Isaka nor Northrup includes any teaching or suggestion of a control valve positioned between a pump and an end of a porous region, or channel or column, of the apparatus disclosed therein.

Isaka, Northrup, and Swedberg

Claims 8 and 26-28 stand rejected under 35 U.S.C. § 103(a) for reciting subject matter which is assertedly unpatentable over the subject matter taught in Isaka, in view of the teachings of Northrup and, further, in view of teachings from U.S. Patent 5,571,410 to Swedberg et al. (hereinafter "Swedberg").

Swedberg teaches separation apparatus, or "total analysis systems," that include substrates that are not formed from silicon or silicon dioxide. Col. 7, lines 53-56. Instead, the substrates of the apparatus that are disclosed in Swedberg may be formed from the following materials: polycarbonates; polyesters, including poly(ethylene terephthalate) and poly(butylene terephthalate); polyamides, (such as nylons); polyethers, including polyformaldehyde and poly(phenylene sulfide); polyimides, such as KAPTON® and UPILEX®; polyolefin compounds, including ABS polymers, Kel-F copolymers, poly(methyl methacrylate), poly(styrene-butadiene) copolymers, poly(tetrafluoroethylene), poly(ethylenevinyl acetate) copolymers, poly(N-vinylcarbazole) and polystyrene. Swedberg, col. 21, line 49 through col. 22, line 4. Swedberg also describes that the substrate of a separation apparatus may be formed from ceramics (including aluminum oxides and the like) and composite substrates, such as laminates. Swedberg, col. 7, lines 56-64.

In some of the embodiments of separation apparatus that are described in Swedberg, the miniaturized columns that have been formed in the substrate are filled with a porous medium, which is made of particles, sheets or membranes. Swedberg, col. 27, lines 33-35. The porous medium is biocompatible and may be made from such materials as nylon, cellulose, polymethylmethacrylate, polyacrylamide, agarose, or the like. Swedberg, col. 27, lines 37-40.

Each of claims 8 and 26-28 is allowable, among other reasons, for depending indirectly from claim 1, which is allowable.

Claims 8 and 26-28 are also allowable since Swedberg teaches away from applying the principles taught therein to apparatus that are formed from silicon or silicon dioxide, like the apparatus that are taught in Isaka and Northrup. Specifically, Swedberg states, as an object of the subject matter taught therein, “avoid[ance of] the inherent chemical activity and pH instability encountered with silicon and prior silicon dioxide-based device substances . . .” Col. 4, lines 52-59; *see also*, col. 7, lines 53-56, describing the “substrate” as “*not* silicon or silicon dioxide material such as quartz, fused silica or glass” (emphasis supplied). Therefore, Swedberg clearly teaches away from the asserted combination of reference teachings.

Further, as Swedberg teaches away from the asserted combination of its teachings with those of both Isaka and Northrup, it is respectfully submitted that one of ordinary skill in the art would not have been motivated to have combined the teachings of Isaka, Northrup, and Swedberg in the manner that has been proposed. It therefore appears that any such motivation could only have been gleaned improperly from the disclosure of the above-referenced application.

Therefore, Swedberg cannot be relied upon to, along with Isaka and Northrup, establish a *prima facie* case of obviousness against any of claims 8, 26-28, or any of the other claims of the above-referenced application.

Isaka, Northrup, and Miura

Claims 14, 15, 17, and 21 are rejected under 35 U.S.C. § 103(a) for being directed to subject matter which is allegedly unpatentable over teachings from Isaka, in view of the teachings of Northrup and, further in view of the subject matter taught in U.S. Patent 5,132,012 to Miura et al. (hereinafter “Miura”).

Claims 14, 15, 17, and 21 are allowable, among other reasons, for depending directly or indirectly from claim 1, which is allowable.

Isaka, Northrup, and Sunzeri

Claim 6 has been rejected under 35 U.S.C. § 103(a) for reciting subject matter which is purportedly unpatentable over teachings from Isaka, in view of the teachings of Northrup and, further, in view of teachings from U.S. Patent 5,536,382 to Sunzeri (hereinafter “Sunzeri”).

Claim 6 is allowable, among other reasons, for depending indirectly from claim 1, which is allowable.

In view of the foregoing, it is respectfully requested that the 35 U.S.C. § 103(a) rejections of claims 1, 3-11, and 13-29 be withdrawn.

ENTRY OF AMENDMENTS

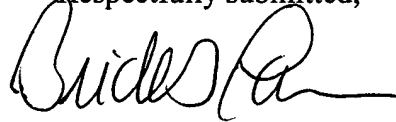
It is respectfully submitted that the proposed amendment to independent claim 1 should be entered because it does not introduce new matter into the above-referenced application, entry thereof would not require an additional search (the subject matter proposed to be incorporated into independent claim 1 is currently recited in claims 13-15), and, by eliminating grounds for rejection, it narrows the number of issues that remain for purposes of appeal.

In the event that the proposed amendment to independent claim 1 is not entered, or if it is determined that the proposed amendment does not place the above-referenced application in condition for allowance, entry thereof is respectfully requested if a Notice of Appeal is filed in the above-referenced application.

CONCLUSION

It is respectfully submitted that each of claims 1, 3-11, and 13-29 is allowable. An early notice of the allowability of each of these claims is respectfully solicited, as is an indication that the above-referenced application has been passed for issuance. If any issues preventing allowance of the above-referenced application remain which might be resolved by way of a telephone conference, the Office is kindly invited to contact the undersigned attorney.

Respectfully submitted,



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